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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/175,713

10/20/98

HERRMANN

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GI-5302-CON

HM22/1214

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EXAMINER

KEMMERER, E

ART UNIT

PAPER NUMBER

1646

4

DATE MAILED:

12/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/175,713

Applicant(s)

Herrmann et al.

Examiner

Elizabeth C. Kemmerer

Group Art Unit

1646



☒ Responsive to communication(s) filed on 20 Oct 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-47 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-47 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 17, 18, drawn to compositions comprising polynucleotides encoding amino-terminal modified chemokines, host cells comprising same and methods of recombinantly expressing same, classified in class 536, subclass 23.5, for example.
- II. Claims 15, 19-28, 44 and 45, drawn to amino-terminal modified chemokines and compositions comprising same, classified in class 514, subclass 2, for example.
- III. Claims 16, 46 and 47, drawn to gene therapy, classified in class 424, subclass 577, for example.
- IV. Claim 29, drawn to an antibody, classified in class 530, subclass 387.1, for example.
- V. Claim 30, drawn to a method of identifying molecules capable of interacting with an amino-terminal modified chemokine, classified in class 436, subclass 501.
- VI. Claims 31-33, drawn to methods of affecting receptor function, classified in class 435, subclass 7.1.
- VII. Claims 34, 35 and 38-43, drawn to therapeutic methods involving amino-terminal modified chemokines as the therapeutic agent, classified in class 514, subclass 2+.
- VIII. Claims 36 and 37, drawn to methods of identifying amino-terminal modified chemokines capable of inhibiting the interaction of HIV with an HIV receptor, classified in class 435, subclass 7.8, for example.

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The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I, II and IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group IV, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group IV can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups III and V-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires administration of transformed cells, which is not required by any of the other groups. Invention V requires

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identification of molecules that interact with chemokines, which is not required by any of the other groups. Invention VI requires measurement of altered receptor function, which is not required by any of the other groups. Invention VII requires administration of a chemokine and consideration of effect on disease, which is not required of any of the other groups. Finally, Invention VIII requires consideration of HIV-HIV receptor binding, which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I can be used to recombinantly express protein *in vitro* or as probes useful in nucleic acid hybridization assays.

The products of Invention I are independent and distinct from the methods of each of Inventions V-VIII, because the methods do not require use of the product.

The products of Invention II are independent and distinct from the method of Invention III, because the method does not require the products.

Inventions II and each of V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

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the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention II can be used to purify or label the corresponding receptors.

The products of Invention IV are independent and distinct from the methods of Inventions III and V-VIII because the methods do not require the products.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) SDF-1 α
- 2) SDF-1 β
- 3) IP-10
- 4) Mig
- 5) GRO α
- 6) GRO β
- 7) GRO γ
- 8) interleukin-8
- 9) PF4
- 10) ENA-78
- 11) GCP-2
- 12) PBP
- 13) CTAP-III

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- 14) β -thromboglobulin
- 15) NAP-2
- 16) C10
- 17) DC-CK1
- 18) CK α 1
- 19) CK α 2
- 20) MCP-1
- 21) MCP-2
- 22) MCP-3
- 23) MCP-4
- 24) MIP-1 α
- 25) MIP-1 β
- 26) lymphotactin
- 27) ATAC
- 28) eotaxin
- 29) eotaxin2
- 30) I-309
- 31) HCC-1
- 32) HCC-2
- 33) HCC-3
- 34) LARC/MIP-3 α
- 35) MIP-3 β
- 36) PARC
- 37) TARC
- 38) 6CKine
- 39) ELC
- 40) SLC
- 41) CK β 4
- 42) CK β 6
- 43) CK β 7
- 44) CK β 8
- 45) CK β 9
- 46) CK β 11
- 47) CK β 12
- 48) CK β 13
- 49) CX3C
- 50) RANTES and
- 51) a chemokines which binds the fusin/CXCR4 receptor.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK
December 13, 1999